

MEMORANDUM FOR Arthur Lyons, LTC, MC, Division of Viral Diseases, Walter Reed Army Institute of Research (WRAIR), 503 Robert Grant Avenue, Silver Spring, MD 20910-7500

SUBJECT: Memorandum #1: Project Does Not Qualify as a Research Activity, **WRAIR #1514A** (Surveillance)

1. A determination was made that the project **WRAIR #1514A**, entitled, "Surveillance of Acute Infectious Respiratory Disease in Select Populations: U.S. Embassy Employees," (version 7, dated 15 December 2008), submitted by Arthur Lyons, LTC, MC, Division of Viral Diseases, WRAIR, does not require review by the WRAIR Institutional Review Board (IRB) in accordance with WRAIR Policy Letter 08-03.
2. This project is surveillance of the causes of acute febrile respiratory disease in personnel located at various U.S. Embassy facilities operated worldwide by the Department of State (DoS). Personnel who self-report with influenza-like illness (ILI) symptoms will be asked to provide a respiratory specimen that will be analyzed for a battery of viral and bacterial pathogens in the Division of Viral Diseases (DVD), WRAIR, using two Food and Drug Administration (FDA) approved devices: the Centers for Disease Control (CDC) influenza RT-PCR assays and the Luminex System. The project is funded by the Department of Defense Global Emerging Infections Surveillance and Response System (DoD GEIS).
3. Upon encountering an individual with respiratory illness, the U.S. Embassy personnel will describe the intent of surveillance and provide an information sheet describing the purpose of the project and potential future uses of the samples. The medical provider will also complete a questionnaire that provides basic demographic information about the individual, including information regarding the clinical presentation of their illness, and collect the respiratory samples. WRAIR investigators will provide aggregate data to the DoS to inform them of the influenza and respiratory pathogens observed in U.S. Embassy employees.
4. A WRAIR Scientific Review Committee approved the project (version 1, dated 4 August 2008) on 9 September 2008. Administrative changes that occurred between the scientifically approved version and the current version of the protocol did not require scientific review.
5. A memorandum of support from the DoS (dated 21 November 2008) was provided to the WRAIR Division of Human Subjects Protection (DHSP) on 5 December 2008.
6. To cover the transfer of samples and data from the U.S. Embassies to WRAIR an agreement is likely needed prior to the initiation of any work. In addition, select influenza isolates may also be sent to the U.S. Air Force School of Aerospace

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Medicine (USAFSAM). This determination does not preclude the need for any agreements to support the transfer of these samples. The investigator should consult with the WRAIR Office of Research and Technology Applications (ORTA) and/or Resource Management to determine which agreements are needed.

Copies of the fully executed documents should be provided to the DHSP once they become available.

7. No additional information is required at this time. However, should the objectives change from those outlined above such that the study is no longer surveillance, the submitted protocol would need an independent determination by the Chair, WRAIR IRB, or the Director, DHSP, as to whether or not the investigator is engaged in human subjects research, and whether or not WRAIR IRB review and approval are required.
8. The point of contact for this action is Melissa P. Ball, M.A., CCRP, at (301) 319 -9974 or at melissa.p.ball@us.army.mil.



R. SCOTT MILLER
COL, MC
Chair, Institutional Review Board
Walter Reed Army Institute of Research

CF:

Julia Lynch, COL, MC

Claudia Golenda, Ph.D., ORTA

Jesse Brogan, Resource Management

MCMR-ZB-P (For information only due to GEIS funding)